# CEJ Ankle Support Report

BMED 456

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## 1. Executive Summary

This document provides information about an ankle support device designed to allow for ankle dorsiflexion and plantar flexion. In this document the product's specifications, objectives and expectations are outlined. Included in this document is background information, stage gate process, prototype design development and considerations, and qualification requirements.

## 2. Introduction and Background

The CEJ is an ankle foot orthosis (AFO). AFOs are intended for users with multiple sclerosis (MS), or other diseases or disorders, who suffer from foot drop. Foot drop is caused by weakness or paralysis of the muscles involved in lifting the front part of the foot, and can be the result of MS, nerve injuries, diabetes, or spinal cord and brain disorders [1]. Current AFO devices only allow for the users foot to be held in dorsiflexion, preventing the front part of the foot from dropping during the swing phase of the gait cycle. While this is an essential aspect of the device, sitting for prolonged periods of time with the foot being held in dorsiflexion can become uncomfortable and can be tiring on the muscles of the lower leg. The CEJ AFO will hold the users foot in dorsiflexion during gait, but also have a buckle release to allow the user to release their foot into plantar flexion while seated.

## 3. Customer Requirements and Design Specifications

### 3.1. IFU

The CEJ Ankle Support is an ankle-foot orthosis (AFO) designed to allow the user to extend their ankle while seated as well as support the ankle in flexion during gait. This AFO has a quick release to allow foot drop. Traditional AFOs do not allow foot drop which causes strain on the ankle when sitting/resting due to the constant ankle flexion. This device is designed to be lightweight, affordable, and safe for the user. The ankle support is aimed to improve mobility and comfort of patients with multiple sclerosis (MS). The device is for use for patients less than 200 lbs.

## 3.2. Product Design Specifications

**Table 1. Product Specification Matrix**

| | Customer Requirement | Engineering Specifications | Rationale | Testing Protocol |
|---|---|---|---|---|
| 1 | Functional | Allows ankle to extend with a quick release mechanism<br><br>The brace's material does not add more than 1 inch to the circumference of the ankle | Device's function is to support ankle in flexion but should allow for ankle extension when desired<br><br>Able to wear under clothes | Functional Week Long Testing to determine if releasing mechanism is effective |
| 2 | Lightweight | Weighs no more than 20 ounces | The upper limit weight of other ankle support devices is 15 ounces | Weigh on a scale |
| 3 | Safe | The ankle support will have no sharp or abrasive parts.<br><br>The ankle support can statically hold 200 lbs and can withstand the impact force associated with a 200 lb user walking.<br><br>The ankle support will prevent hyperextension of the knee. | The user should not be harmed when using the product.<br><br>The user should be able to move without the product breaking and causing harm to the user. | Functional Week Long Testing to determine if any irritation or worse harm is caused to the user |
| 4 | Affordable | Cost does not exceed $300.00 | Similar ankle support devices have a cost of about $160.00 | Calculate the cost of manufacturing, materials, and distribution |
| 5 | Durable | Able to withstand pressures of foot when in flexion and extension up to 250 lbs<br><br>Temperature resistant (0-120 F)<br><br>Humidity Resistance (90%) | Needs to be able to support weight of a user in multiple environments. | Fatigue testing under maximum weight (250 lbs) |

The product specification matrix, as seen in Table 1, as well as other specifications were used to conduct a conjoint analysis to determine the most important customer requirements.

**Table 2. Product Design Factors and Levels.**

| **Factor** | **Level 1 (1)** | **Level 2 (0)** |
|---|---|---|
| Cost | $100 | $115 |
| Weight | 10oz | 12oz |
| flexibility | keeps foot in dorsiflexion | allows plantar flexion |
| rigidity | no flex with movement of the leg | allows some flex with movement of the leg |
| strap | velcro | strap with a snap |
| locking mechanism | three click release | button release |
| height | 12 in | 14 in |

A regression analysis of variance was conducted on eight different conjoint cards of the different levels for the design to determine the most important factors. The conjoint cards were then voted on from best to worst by classmates. Based on the data obtained from our classmates, the cost is the most important factor (p-value = 1.06E-05) and rigidity (p-value = 0.043) was another. Rigidity was a factor we originally didn't think would be too significant, so we were surprised when it was one of the lower p-values. After talking to our sponsor, we found that it is actually one of the more important factors. This is due to the fact that it can prevent knee hyperextension. Cost was a factor we expected to be important, and we are planning on keeping the price low. The regression analysis of variance also revealed which level was most important. For cost, the conjoint analysis revealed that a cost of $115 is preferred to $100. As for rigidity, the conjoint analysis revealed that a some flex is important to customers but we have to be sure not to compromise the prevention of hyperextension. A factor that was not found to be important but is, is the ability to allow the foot to go into plantar flexion, not just being kept in dorsiflexion at all times.

### 3.3. House of Quality

**Table 3. House of Quality (Rooms 1, 2, 4, 5, 6)**

| | | Engineering Characteristics | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Improvement Directions | | ↓ | ↓ | | ↑ | ↓ | ↑ | ↑ | ↑ | ↓ | ↑ | | | |
| Units | | $lbs_f$ | % | Degrees | Degrees | Oz | n/a | psi | psi | $lbs_f$ | n/a | Competitor Rankings | | |
| Customer Requirements | Importance Weight Factor | Quick release ease | Jamming probability | Angle support in flexion | Angle at rest | Weight | Weather resistance | Material strength | Material stiffness | Straps release ease | Comfortability | OSSUR AFO Leaf Spring Foot Drop Brace | Swedish Ankle Foot Orthosis | OSSUR AFO Dynamic Drop Orthosis |
| Allows Plantar Flexion | 5 | 9 | 9 | | 9 | | | | | | | 1 | 1 | 1 |
| Lightweight | 4 | | | | | 9 | | 3 | | | | 4 | 4 | 4 |
| Safe: Prevents hyperextension | 5 | | | | | | | 9 | | | | 2 | 2 | 2 |
| Affordable | 3 | 3 | | | | | | 3 | 3 | 3 | | 5 | 5 | 2 |
| Durable | 4 | | | | | | 9 | 9 | 9 | | | 3 | 4 | 4 |
| **Raw Score** (372) | | 54 | 45 | 0 | 45 | 36 | 36 | 102 | 45 | 9 | 0 | | | |
| **Relative Weight %** | | 14.5 | 12.1 | 0 | 12.1 | 9.7 | 9.7 | 27.4 | 12.1 | 2.4 | 0 | | | |
| **Rank Order** | | 2 | 3 | 9 | 3 | 6 | 6 | 1 | 3 | 8 | 9 | | | |

The house of quality, shown in Table 3, was used to determine the most important engineering characteristic, based on our customer requirements. It was determined that the material strength was the most important engineering characteristic, as it had influences on the weight, the safety, the price, and the durability of the product.

## 4. Stage Gate Process

### 4.1. Concept Review

On February 20th, 2019, group members presented a concept review of the CEJ Ankle Support. The presentation included the following: background information, Indication For Use (IFU), Total Available Market (TAM), Regulatory Plan, Modified Budget, Project Plan, House of Quality, Failure Mode and Effects Analysis (FMEA), Hazard and Risk considerations, Potential Concepts Considered, Pugh Chart, and Front Runner Design description. A few of the presented topics can be found throughout the report. Below are the topics not already previously covered in the report.

*Total Available Market (TAM)*

The TAM was defined by identifying how many individuals have multiple sclerosis in the U.S. There are at least 400,000 individuals in the U.S with MS, with 200 new cases being diagnosed each week [3]. Foot drop is a common symptom of MS along with nerve injuries, diabetes, and spinal cord and brain disorders [1]. Foot drop is caused by weakness or paralysis of the muscles involved in lifting the front end of the foot. Because foot-droop is a common symptom in patients with MS, it is estimated that each individual can make use of the CEJ Ankle Support. If our device is roughly $100, the TAM is approximately $40,000,000.

*Regulatory Plan*

The CEJ is a Class 1 Device and is 510K exempt.

*Potential Concepts Considered*

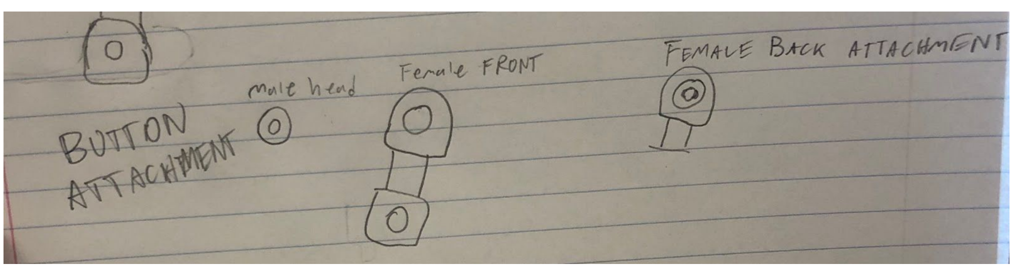



**Figure 1. Concept 1: Button Release**

Concept 1, figure 1:  A button release to allow the foot to be released from dorsiflexion to plantar flexion. The male head will be attached to the rubber joint that’s attached on the lower half of the ankle support. The female back attachment will attached to the calf support/upper half of the ankle support. When clipped the ankle support will hold the foot in a dorsiflexed position. When unclipped the ankle will have the ability to go into plantar flexion.

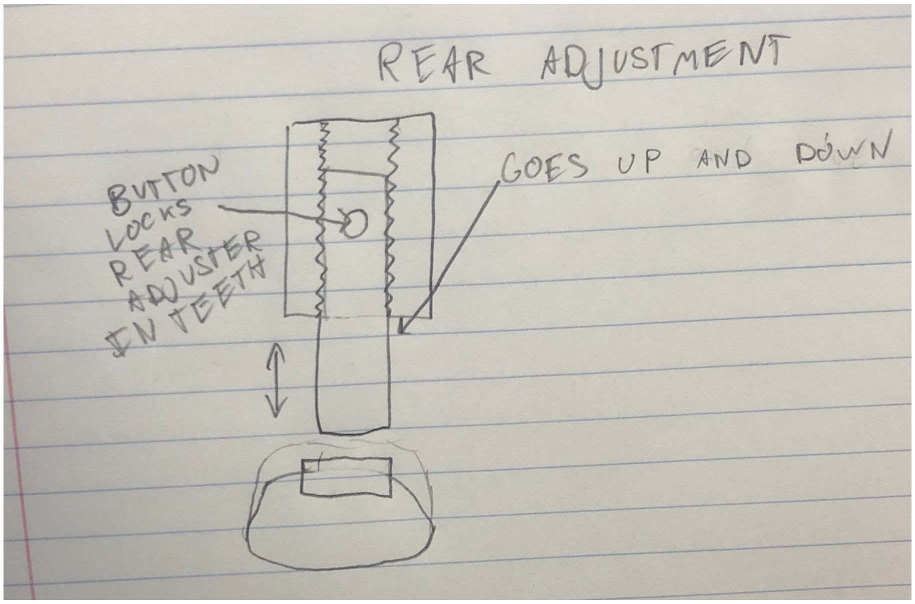



**Figure 2. Concept 2: Rear Bar Extension**

Concept 2, figure 2: A bar extension on the back of the brace, that when fully down holds the ankle in dorsiflexion, and when fully up allows the ankle to fall into plantar flexion. Both pieces of the ankle support brace will be very similar to the existing brace our patient currently wears, however, the rear adjustment will replaces the stopper currently in place. The bar will push down on the heel cup and raise the ankle into dorsiflexion. When the bar is up it allows the heel cup and ankle to be in a plantar flexed position.

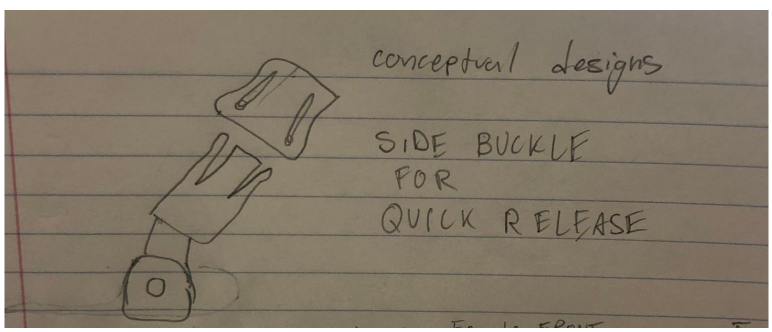



**Figure 3. Concept 3: Double Sided Buckle Release**

Concept 3, figure 3: A double side release buckle that when clicked into the buckle holds the foot in dorsiflexion, and when unclicked from the buckle allows the joint to release and get longer, and allow the foot to fall into plantar flexion.  This brace would use a similar joint mechanism to the brace currently being used, but the rubber joint on this brace could be released by the buckle.

Our third concept, the buckle release, was determined to be the most beneficial design concept.  This concept was compared to the other two concepts we've developed and the "gold standard" brace, the Swedish AFO.  The design we selected was found to be similar in price to the Swedish AFO and cheaper to manufacture than the other two designs.  This brace was also similar to the gold standard or the others, or better than the standard in the other preferred areas.  The difference in cost than the other two was the primary determination in selecting the buckle design over the button and the posterior extension bar.  The selected design had similar pluses that applied to the other two as well, but this design had no negatives.

### 4.2 Design Freeze

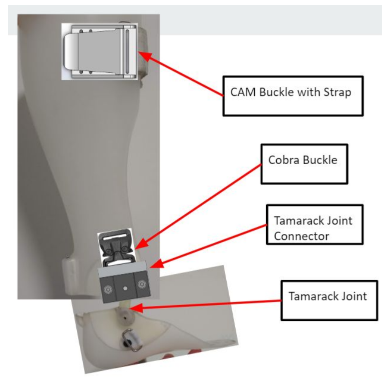



**Figure 4. Mock-up of final design**

### 4.3 Design Review

The use of a clip will allow for extension of the ankle.  Just connecting the Tamarack Joint directly to the buckle could allow the possibility of rotation of the joint and the buckle at the connection point to the brace.  To reduce the possibility of rotation, we secured the buckle with sheet metal, providing 2 connection points at the brace, and a 3D printed joint attachment to the buckle, also to give 2 connection points.  These adjustments allow for extra strength and stability of the joint.

## 5. Description of Final Prototype Design

### 5.1 Overview

The final prototype design utilizes COBRA buckles along with some aluminum sheet metal and a 3D printed Tamarack Joint attachment to allow for the option of extension.

### 5.2 Design Justification

This design fulfills the customer requirements of providing flexion of the ankle during the swing phase of the gait cycle, while allowing extension while the user is seated.  The clip allows for release of the joint, while the sheet metal and the 3D printed Tamarack Joint attachment provide stability of the joint and a connection to the clip.

### 5.3 Analysis

The final prototype was able to prevent foot-drop by holding the foot at about 83° in dorsiflexion.  The release also allowed for a more comfortable seated position of the ankle in plantar flexion.  While these metrics were met, the prevention of hyperextension of the knee was not accomplished.

5.4 Cost Breakdown

The cost breakdown can be seen in the budget, Table 8, in Appendix G. The breakdown only accounts for the materials used to make the brace. There the manufacturing and testing machines were not allotted for because they were available at no cost in labs on campus.

5.5 Safety Considerations

For our safety, we will be using heat resistant gloves to handle the hot polypropylene when modeling the device around the mold of the users leg. For the users safety, we will test each material extensively to ensure the durability of each piece to be sure it will not fail during use.

## 6. Prototype Development

6.1. Model Analyses

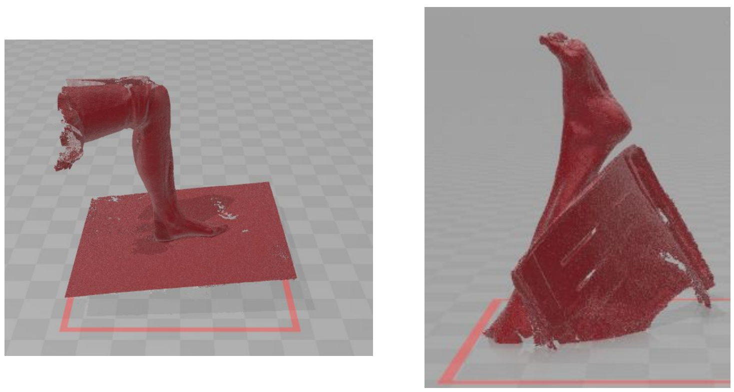


**Figure 5. 3D scan of the patient's leg to create a positive mold from.**

Using a 3D scan of the patient's leg to mold the polypropylene of our AFO. The foot mold will allow to create a comfortable mold around her ankle for optimal fit and comfort around a rigid part of the body.

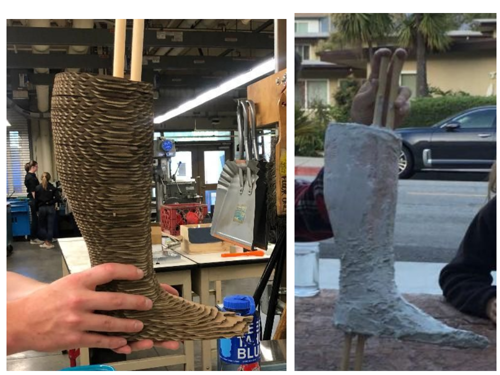


**Figure 6. The stacked cardboard slices from the 3D leg model, and the model covered in Bondo**

6.2. <u>Evolution of Prototypes</u>

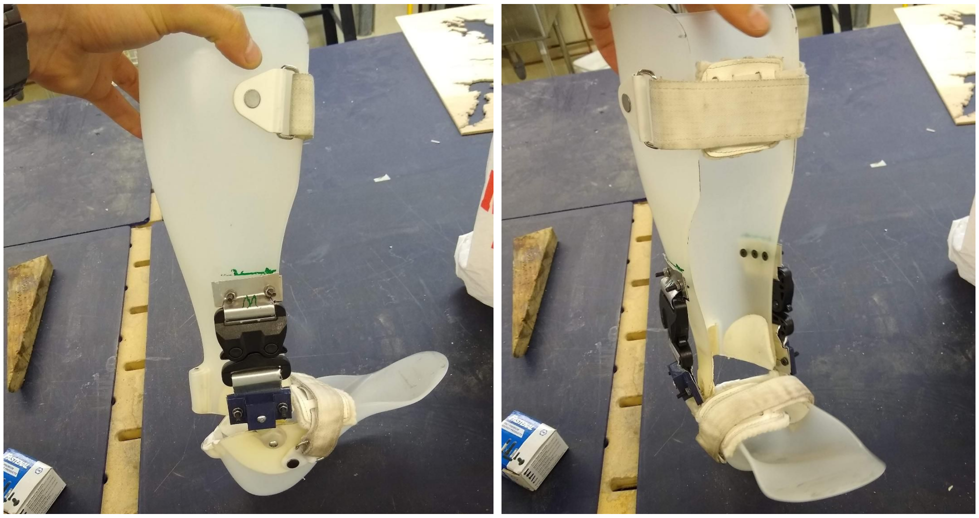


**Figure 7. Front and side views of preliminary prototype**

**Figure 8. Front and side views of final prototype**

The prototypes will be tested in tension and compressive forces to determine if the side-release buckles will be strong enough to withstand the weight transfer during walking. If the tensile force of the side-release buckle is stronger than the Tamarack side joints then our only worries is fatigue and impact causing the side-release buckle to fail.

## 6.3 Manufacturing Process

1. Scan foot and ankle using a camera (XBOX 360 Kinect) to produce 3D Model.

    1.1 ReconstructMe and an Xbox Kinect camera were used to scan and create a 3D computer model of the lower leg and foot.

2. Produce a smooth mesh of the 3D model, and create slices of the model.

    2.1 MeshLab and Autodesk Meshmixer were used to crop out the unwanted excess pieces of the 3D computer model from background objects, and to create a smooth mesh model of the lower leg.

    2.2 Autodesk Fusion 360 and Slicer for Fusion 360 were used to break the leg model into slices that can be cut out and stacked to make a physical model

3. Use a laser cutter to cut out the slices from step 2, and stack the slices to create a physical model.

4. Cover model with Bondo.

5. Vacuum form polypropylene to mold.

    5.1 Heat polypropylene to 380 F

    5.2 Move oven back, so it is no longer over the polypropylene sheet

    5.3 Raise the platform with the mold to the heated polypropylene sheet

    5.4 Turn on the vacuum to allow the sheet to form around the mold

6. Add attachments.

    6.1 Align the Tamarack Joint so that it sits right on the lateral malleolus and the medial malleolus and mark the corresponding point on the foot piece where the attachment screw should be placed

    6.2 Mark on the calf piece where the top part of the Tamarack Joint lines up

    6.3 Measure up from that point about 4 inches and drill 2 holes about 1.5 inches apart for the aluminum connection

    6.4 Loop the aluminum through both ends of the COBRA buckle, and attach the top end to the 2 drilled holes, and attach the bottom part to the 3D printed joint attachment

6.5 Attach the Tamarack Joint to the 3D printed attachment and attach the bottom part of the joint to the foot piece

6.6 Place padding over the screw heads on the interior of the brace

### 6.4 Divergence Between Final Design and Final Functional Prototype

The final prototype does not deviate from the final design, but it does from the preliminary functional prototype. The preliminary functional prototype did not account for the curvature of the calf piece of the brace, so with the modified joint pieces, the calf and the foot pieces were slightly unaligned. For our final prototype, we flattened the sides to allow for a straight connection.

## 7. IQ/OQ/PQ

### 7.1. DOE

**Table 4. Design of Experiments**

| Engineering Metric | Specification | Test Method | Test Apparatus Location | Apparatus Experience / Training | Sample Size | Power |
|---|---|---|---|---|---|---|
| Costs less than $300 | The budget give to us by the BMED department, and external funding | Make sure all modifications to brace cost < $300 | Anywhere, computer tracking receipts | None | 1 | 95% |
| Fits as well as current brace | Want to make sure the support fits on Denise as well as | Put ankle support on Denise to verify the fit. | Anywhere Denise and Kim are. | Nurse/ Physician Training (Kim) | 1 | 100% |
| Tamarack joint - Ultimate Strength* | The hinge needs to be strong enough to withstand forces associated with the ankle | Tension/ Compression test to find the Ultimate Strength of the hinge | 192-135 | Bluehill software manual needs to be followed. Minimal Experience | 10 | 95% |

| | | | | | | |
|---|---|---|---|---|---|---|
| Tamarack joint - Fatigue Testing* | The hinge needs to be durable enough to withstand the many times denise stands and sits throughout the day | Cyclic/ Fatigue Testing | 192-135 | Fatigue testing training | 5 | 95% |
| Polypropylene- Fatigue Testing* | The support structure needs to be able to support the patient's weight | Tension/ Compression test to find the Ultimate Strength | 192-135 | Bluehill software manual needs to be followed. Minimal Experience | 5 | 95% |
| Tamarack Connector pull out strength | The connector needs to be able to withstand the static and dynamic forces applied when in use. (200 lbf / 2 sides) * 3(F.O.S) = 300lbf | Tension test to find the Ultimate Strength | 192-135 | Bluehill software manual needs to be followed. Minimal Experience | 5 | 95% |
| Sheet Metal pull out strength | The sheet metal connection needs to be able to withstand the static and dynamic forces applied when in use. (200 lbf / 2 sides) * 3(F.O.S) = 300lbf | Tension test to find the Ultimate Strength | 192-135 | Bluehill software manual needs to be followed. Minimal Experience | 5 | 95% |

* These engineering metrics will not be tested as they are not products we have designed and have been tested to work in our application.

The design of experiments, Table 4, shows the engineering metrics important to this device and the tests necessary to determine the individual pieces reliability. These testing protocols were necessary to ensure the overall reliability and effectiveness of the device.

7.2 Verification and Validation

The brace could withstand a tensile force up to 277.9lbs, shown in figure 9. In compression, the brace folded in half at the joint under 200lbs of compression and did not break at any point. For the specifications, it met most requirements, Table 5, but was not able to prevent hyperextension of the knee.

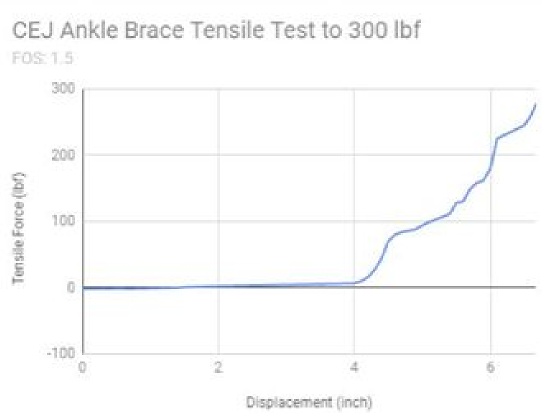



**Figure 9. Graph from tensile test results**

**Table 5. Verification and validation of device specifications**

| **Specifications** | **Engineering Metric** | **Results** | **Requirement Met? (Y/N)** |
|---|---|---|---|
| Allows ankle to extend with a quick release mechanism | Measure angle ankle when released from dorsiflexion, minimum 30° | Ankle angle increases 36.845° | Y |
| The brace's material does not excessively add to the circumference of the ankle | Measure circumference of device, ensure it is less than 2.5 inch larger than ankle circumference | 11 11/16 in -9 5/16 in=2 3/8 in | Y |
| Weight | Weighs no more than 20 ounces | 17.45 oz | Y |
| The ankle support will have no sharp or abrasive parts. | Sand all parts | Smooth edges | Y |

| | | | |
|---|---|---|---|
| Withstand static and impact forces associated with user walking | 200 lb tension/compression test for Cobra Buckle, Tamarack connector, and sheet metal assembly | Withstood 277.9 lbs in tension, 200 lbs in compression. Polypropylene used for current application, impact forces not tested. | Y |
| Cost | Less than $300 | $176.58*<br><br>*Does not include shipping and handling | Y |
| Attachments withstand pressures of foot when in dorsiflexion and plantar flexion. | 200 lb tension/compression test for Cobra Buckle, Tamarack connector, and sheet metal assembly | Withstood 277.9 lbs in tension, 200 lbs in compression. | Y |
| Prevent hyperextension of the knee. | Measure angle of knee between mid-stance and toe off of gait cycle. Ensure less than 23° | >23° | N |

## 8. Conclusions and Recommendations

### 8.1 Recommendations

Some recommendations for future models of this brace would be the integration of a guide wire for the COBRA buckle, the use of buckles with a shorter male head, rounding out the body of the brace, and setting the buckle into the polypropylene. The addition of the guide wire and the shorter male head would allow for more easy reattachment of the joint to regain the flexion held position. The buckles being set into the polypropylene and the rounding out of the body of the brace would reduce the bulk of the brace.

### 8.2 Conclusions

We found that the brace was able to prevent foot drop by holding the foot in dorsiflexion during gait, but it wasn't able to prevent hyperextension of the knee. We also came across some issues with the molding process, but through trouble-shooting the process, we were able to achieve a polypropylene mold from the Bondo/ cardboard mold of the user's calf. We also found that her current brace was not a perfect mold of her lower leg, and was slightly bigger than the mold we created.

## 9. Acknowledgements

The development of the CEJ would not have been possible without the support of our sponsors Kim Chartrand, Denise and David West, Senior Project faculty advisors John Gerrity

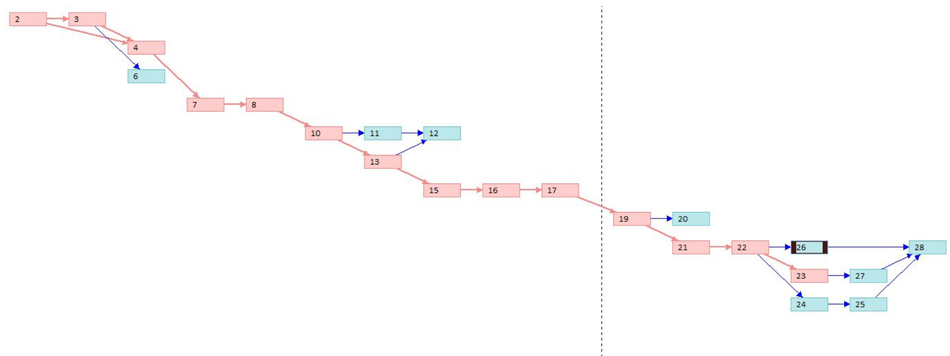
and Dr. Whitt, our financial sponsor Dr. Christopher Porterfield and the Engineering Department at California Polytechnic State University in San Luis Obispo.

## 10. Appendices

### 10.1. Appendix A: References


[1] Foot Drop Symptoms and Causes. Mayo Clinic.


### 10.2. Appendix B: Project Plan (PERT Chart)




| | Task Mode | Task Name | Duration | Start | Finish |
|---|---|---|---|---|---|
| 1 | | **Project Specifications** | **13 days** | **Mon 1/14/19** | **Wed 1/30/19** |
| 2 | | Overall product specifications | 1 wk | Mon 1/14/19 | Fri 1/18/19 |
| 3 | | Hardware Specifications | 4 days | Mon 1/21/19 | Thu 1/24/19 |
| 4 | | Market Research | 4 days | Fri 1/25/19 | Wed 1/30/19 |
| 5 | | **Supplier Specifications** | **15 days** | **Fri 1/25/19** | **Thu 2/14/19** |
| 6 | | Hardware | 4 days | Fri 1/25/19 | Wed 1/30/19 |
| 7 | | Market Research | 4 days | Thu 1/31/19 | Tue 2/5/19 |
| 8 | | Concept Review | 7 days | Wed 2/6/19 | Thu 2/14/19 |
| 9 | | **Product Design** | **15 days** | **Fri 2/15/19** | **Thu 3/7/19** |
| 10 | | Hinge | 1 wk | Fri 2/15/19 | Thu 2/21/19 |
| 11 | | Outer Cover | 1 wk | Fri 2/22/19 | Thu 2/28/19 |
| 12 | | Functionality | 1 wk | Fri 3/1/19 | Thu 3/7/19 |
| 13 | | Straps | 3 days | Fri 2/22/19 | Tue 2/26/19 |
| 14 | | **Project Integration** | **18 days** | **Wed 2/27/19** | **Fri 3/22/19** |
| 15 | | Prototypes Designed | 8 days | Wed 2/27/19 | Fri 3/8/19 |
| 16 | | Design Freeze | 4 days | Mon 3/11/19 | Thu 3/14/19 |
| 17 | | Preliminary Prototype Plan | 6 days | Fri 3/15/19 | Fri 3/22/19 |
| 18 | | **Next Quarter** | **55 days** | **Mon 4/1/19** | **Fri 6/14/19** |
| 19 | | Test and Manufacturing Plan Presentation | 4.2 wks | Mon 3/25/19 | Mon 4/22/19 |
| 22 | | Functional Prototype Presentation | 31 days | Mon 5/6/19 | Mon 6/17/19 |
| 23 | | Project Report Draft Due | 17 days | Mon 5/6/19 | Tue 5/28/19 |
| 24 | | Poster Due | 17 days | Mon 5/6/19 | Tue 5/28/19 |
| 25 | | Project Expo | 4 days | Tue 5/28/19 | Fri 5/31/19 |
| 26 | | Final Design and Prototype Presentation | 21 days | Mon 5/6/19 | Mon 6/3/19 |
| 27 | | Final Report | 26 days | Wed 5/8/19 | Wed 6/12/19 |
| 28 | | Give Denise Brace | 1 day | Fri 6/14/19 | Fri 6/14/19 |
| 20 | | Tensile Testing At MATE | 22 days | Tue 4/23/19 | Wed 5/22/19 |
| 21 | | Assemble Prototype | 10 days | Tue 4/23/19 | Mon 5/6/19 |

**Figure 10.  PERT Chart through spring quarter**

## 10.3. Appendix C: CAD Drawings

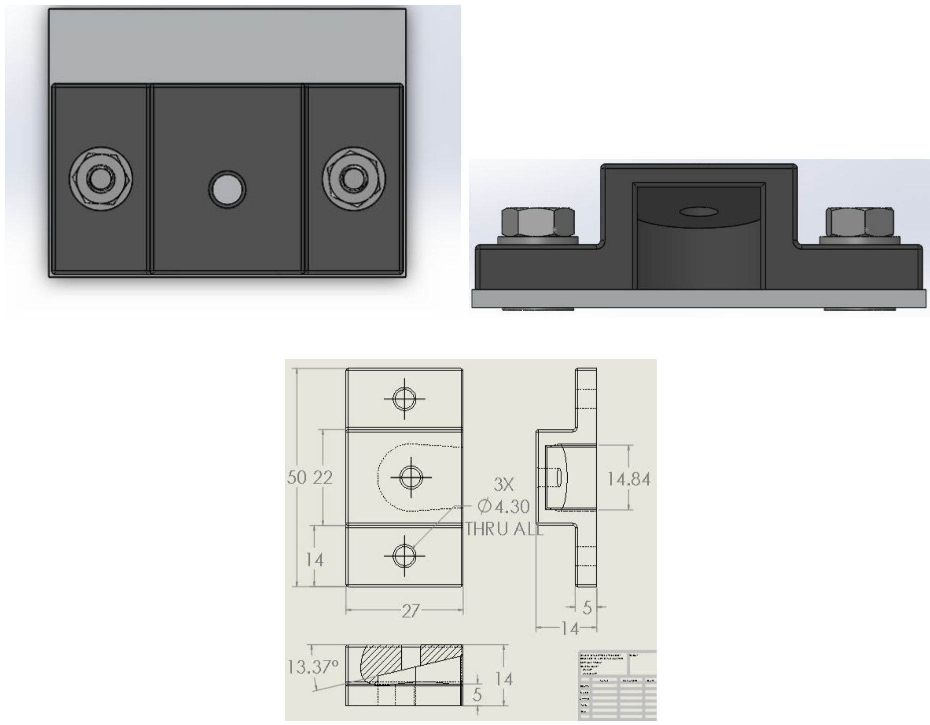



**Figure 11. CAD drawing of 3D printed joint attachment.**

10.4. Appendix D: FMEA, Hazard & Risk Assessment

**Table 6. Failure Mode and Effects Analysis (FMEA)**

| Component Name | Possible Failure Mode | Type | Cause of Failure | OCC | DET | SEV | RPN | Effect of Failure on System | Failure Improvement Alternative Actions (actions to fix the problem… ) |
|---|---|---|---|---|---|---|---|---|---|
| COBRA Buckle | broken | C | improper use of the buckle, or being crushed under high pressure could cause the buckle to break | 4 | 6 | 6 | 144 | would keep ankle in plantar flexion, wouldn't provide dorsiflexion support | perform stress tests on the material used to make the buckle to make sure it won't break under slightly higher pressures than would normally be applied |
| Velcro | worn | C | inadequate use, user applies too much wear and tear, dirt and water | 5 | 5 | 5 | 125 | could impact the device being held in place | testing the velcro under unusual circumstances to ensure reliability |
| Polyester strap | worn | C | extra strain applied to it due to improper use | 2 | 3 | 5 | 30 | wouldn't hold the leg piece and the foot piece together when the buckle is released to allow plantar flexion | repeated stress tests to be sure that the strap can handle repeated use and stresses |
| Tamarack Joint (M-95) | worn | M | Manufactured incorrectly | 2 | 2 | 6 | 24 | would prevent the ankle from being held in dorsiflexion | preform repeated stress tests to be sure the joint won't fail after repeated use |
| Polypropylene | cracked | W | improper manufacturing of material, wears out too easily | 3 | 1 | 5 | 15 | if the crack grows, device could be unusable | stress tests to be sure the polypropylene will withstand the basic pressures applied by the user |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Metal strap loop | bent | C | improper use, being used for more than the design allows | 3 | 1 | 5 | 15 | would impact the strap, could make uncomfortable or difficult to use strap | pressure test to be sure the loop won't bend under unusual pressure |
| Rivet | bent | C | improper use, user applies too much pressure, using for improper activities | 3 | 1 | 5 | 15 | would impact the release from dorsiflexion | stress test to be sure that repeated use and release of the joint won't affect the piece |

The FMEA, Table 6, shows the components of the device that have the highest potential of failure. We determined that the double sided buckle was the most significant, due to the fact that if it fails, the device will no longer be able to maintain the support in dorsiflexion. This is crucial, as the dorsiflexed position is the primary goal of this device.

**Table 7. Hazard and Risk Assessment**

| Description of Hazard | Planned Corrective Action | Planned Date | Actual Date |
|---|---|---|---|
| User of ankle support can venture into extreme environmental conditions such as fog, humidity, cold, and hot temperatures. | Ankle support will be water resistant and made from high and low temperature resistant materials. | 1/27/2019 | 1/30/19 |
| Burns from molding Polypropylene to positive model of leg. | Heat resistant gloves and careful handling of heat remoldable polypropylene. | 2/16/2019 | 6/4/19 |

The hazards and risks, are precautions, possible from the manufacturing and use of this device are shown in Table 7. We will follow safety regulations along with taking extra precautions to prevent burns, and we will test the materials to prevent injury to the user.

### 10.5. Appendix E: Pugh Chart

**Table 8. Pugh Chart**

| | | Concepts | | |
|---|---|---|---|---|
| Criteria | Swedish AFO | 1 | 2 | 3 |
| Cost | D A T U M | - | - | S |
| Weight | | S | S | S |
| Allows Plantar Flexion | | + | + | + |
| Prevents Knee Hyperextension | | + | + | + |
| Durable | | S | S | S |
| # of Pluses | | 2 | 2 | 2 |
| # of Minuses | | 1 | 1 | 0 |

The Pugh Chart, Table 8, shows our three proposed concepts compared to a current device available on the market that is similar to the custom device the user is currently using. We found that the double sided buckle release would be the best of our three concepts for accomplishing the user's desired specifications.

### 10.6. Appendix F: Vendor Information, Specifications, and Data Sheets

McMaster-Carr: https://www.mcmaster.com/

Kingsley Orthotic and Prosthetic Supply: http://www.kingsleymfg.com/KMFGStore/Default.asp

Fastenal: https://www.fastenal.com/

10.7. Appendix G: Budget

**Table 9. Budget**

| Item Description | Manufacturer/ Distributor | Product Number | Purpose | Associated Task | Planned | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Unit | Quantity | Cost/Unit | Total Cost |
| Light-Duty Cam Buckles | McMaster Carr | 29705T31 | To fasten strap | Keep strap locked | 1 | 5 | $15.84 | $15.84 |
| Low-Stretch Polyester Webbing | McMaster Carr | 3444T21 | Strap to attach support to ankle | Keep support on ankle | 5 | 1 | $0.67 | $6.70 |
| Polypropylene Sheet (3/16”) | McMaster Carr | 2898K42 | Distribute load on ankle | Support the ankle | 1 | 1 | $26.81 | $26.81 |
| Tamarack Joint* | Kingsley | B742-85-M | Provide semi-rigid support | Allow attachment of supports, allow smooth gait pattern | 2 | 1 | $33.59 | $33.59 |
| Sheet Metal (Aluminum) | McMaster Carr | 9015T131 | Provide attachment from buckle to brace | Keeps buckle in a rigid position | 1 | 1 | $14.14 | $14.14 |
| GT COBRA Quick Release Buckle | AustriAlpin | PLH-SRB-COB-000 | To allow joint release | Allows for release from flexion to extension | 2 | 2 | $10.00 | $20.00 |
| Resilient Polyurethane Foam Sheet | McMaster Carr | 86375K111 | Provide comfort and support for the foot in the brace | Allow for non direct skin to polypropylene contact | 1 | 1 | $11.18 | $11.18 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Metric 18-8 Stainless Steel Hex Drive Flat head Screws | Fastenal | 11547539 | Provide connection between COBRA buckle, sheet metal, and brace | Allow for the various pieces making up the releasable joint to connect to each other and the brace | 1 | 10 | $23.20 | $23.20 |
| Metric Medium-Strength Steel Hex Nuts | McMaster Carr | 90592A090 | Screw joint to attachment | Holds the screw in place | 1 | 100 | $1.32 | $1.32 |
| Heat-Set Inserts for Plastic | McMaster Carr | 94459A150 | Provide a strong hold for the bolt in the plastic | Allow for the bolt to thread into the polypropylene | 1 | 50 | $9.37 | $9.37 |
| Washers | McMaster Carr | 93475A230 | Prodive distribution of the pressure on the nut evenly over the surface | Allow for distribution of pressure, and provide a flat surface for the nut to sit against | 1 | 100 | $1.86 | $1.86 |
| Bondo | McMaster Carr | 92930A420 | To cover the mold of the patients lower leg | To allow for the part to be molded around the model | 1 | 32oz | $12.57 | $12.57 |
| | | | | | | | **Total** $176.58* | |

Our current projected budget is shown in Table 9. Our total allocated budget is $200, so we are currently about $25 below our total amount. Having this buffer room will be beneficial for the possibility of prototypes that don't work as well as planned. *The total doesn't account for shipping and handling.

10.8. Appendix H: DHF

*Engineering Specifications and Product Specifications*

**Table 10. Product Specification Matrix**

| | Customer Requirement | Engineering Specifications | Rationale | Testing Protocol |
|---|---|---|---|---|
| 1 | Functional | Allows ankle to extend with a quick release mechanism<br><br>The brace's material does not add more than 2 inches to the circumference of the ankle | Device's function is to support ankle in flexion but should allow for ankle extension when desired<br><br>Able to wear under clothes | Functional Week Long Testing to determine if releasing mechanism is effective |
| 2 | Lightweight | Weighs no more than 10 ounces | The upper limit weight of other ankle support devices is 11.5 ounces | Weigh on a scale |
| 3 | Safe | The ankle support will have no sharp or abrasive parts.<br><br>The ankle support can statically hold 200 lbs and can withstand the impact force associated with a 200 lb user walking.<br><br>The ankle support will prevent hyperextension of the knee. | The user should not be harmed when using the product.<br><br>The user should be able to move without the product breaking and causing harm to the user. | Functional Week Long Testing to determine if any irritation or worse harm is caused to the user |
| 4 | Affordable | Cost does not exceed $300.00 | Similar ankle support devices have a cost of about $160.00 | Calculate the cost of manufacturing, materials, and distribution |
| 5 | Durable | Able to withstand pressures of foot when in flexion and extension up to 250 lbs<br><br>Temperature resistant (0-120 F)<br><br>Humidity Resistance (90%) | Needs to be able to support weight of a user in multiple environments. | Fatigue testing under maximum weight (250 lbs) |

*Design History Record (DHR)*

**Table 11. Design History Record**

| Process | Completed by | Expected Date | Actual Date |
|---|---|---|---|
| 3D scan of leg | James Baldwin, Erik Espinoza | 2/25/19 | 2/25/19 |
| Laser cut cardboard slices | James Baldwin, Erik Espinoza, Christine Prothe | 4/10/19 | 4/17/19 |
| Stack cardboard slices to create mold | James Baldwin, Erik Espinoza, Christine Prothe | 4/10/19 | 4/17/19 |
| Cover mold in Bondo | Christine Prothe | 4/30/19 | 5/1/19 |
| Create joint piece | James Baldwin, Erik Espinoza | 5/1/19 | 5/1/19 |
| Test Prototype | James Baldwin, Erik Espinoza, Christine Prothe | 5/22/19 | 5/24/19 |
| Mold final brace piece | James Baldwin, Erik Espinoza, Christine Prothe | 5/29/19 | 6/4/19 |
| Create final prototype | James Baldwin, Erik Espinoza | 5/29/19 | 6/5/19 |

*Manufacturing Process Instructions (MPI)*

1. Scan foot and ankle using a camera (XBOX 360 Kinect) to produce 3D Model.

    1.1 ReconstructMe and an Xbox Kinect camera were used to scan and create a 3D computer model of the lower leg and foot.

2. Produce a smooth mesh of the 3D model, and create slices of the model.

    2.1 MeshLab and Autodesk Meshmixer were used to crop out the unwanted excess pieces of the 3D computer model from background objects, and to create a smooth mesh model of the lower leg.

    2.2 Autodesk Fusion 360 and Slicer for Fusion 360 were used to break the leg model into slices that can be cut out and stacked to make a physical model

3. Use a laser cutter to cut out the slices from step 2, and stack the slices to create a physical model.

4. Cover model with Bondo.

5. Vacuum form polypropylene (4) to mold.

    5.1 Heat polypropylene to 380 F

    5.2 Move the oven back from the polypropylene sheet

    5.3 Raise the mold to the heated polypropylene sheet

    5.4 Turn on the vacuum to allow the sheet to form around the mold

6. Add attachments.

    6.1 Align the Tamarack Joint (1) so that it sits right on the lateral malleolus and the medial malleolus and mark the corresponding point on the foot piece where the attachment screw should be placed

    6.2 Mark on the calf piece where the top part of the Tamarack Joint lines up

    6.3 Measure up from that point about 4 inches and drill 2 holes about 1.5 inches apart for the aluminum connection

    6.4 Loop the aluminum (5) through both ends of the COBRA buckle (6), and attach the top end to the 2 drilled holes, and attach the bottom part to the 3D printed joint attachment (12)

    6.5 Attach the Tamarack Joint to the 3D printed attachment and attach the bottom part of the joint to the foot piece

    6.6 Place padding (7) over the screw heads on the interior of the brace

*Installation Qualification (IQ) and Operations Qualifications (OQ)*

**Table 12. Installation Qualification**

| Item # | Part Number | Part Name | Supplier/ Manufacturer |
|---|---|---|---|
| 1 | B742-85-M | Tamarack Joint | Kingsley |
| 2 | 29705T31 | Light-Duty Cam Buckles | McMaster Carr |
| 3 | 3444T21 | Low Stretch Polyester Webbing | McMaster Carr |
| 4 | 2898K42 | Polypropylene Sheet (3/16”) | McMaster Carr |
| 5 | 9015T131 | Sheet Metal (Aluminum) | McMaster Carr |
| 6 | PLH-SRB-COB-000 | GT COBRA Quick Release Buckle | AustriAlpin |
| 7 | 86375K111 | Resilient Polyurethane Foam Sheet | McMaster Carr |
| 8 | 94459A150 | Heat-Set Inserts for Plastic | McMaster Carr |
| 9 | 11547539 | Metric 18-8 Stainless Steel Hex Drive Flat Head Screws | Fastenal |
| 10 | 90592A090 | Metric Medium-Strength Steel Hex Nuts | McMaster Carr |
| 11 | 93475A230 | 18-8 stainless steel washers | McMaster Carr |
| 12 | N/A | Tamarack Joint connector | 3D printed - Innovation Sandbox (197-205) |

**Table 13. Operations Qualifications**

| Specifications | Engineering Metric | Results | Requirement Met? (Y/N) |
|---|---|---|---|
| Allows ankle to extend with a quick release mechanism | Measure angle ankle when released from dorsiflexion, minimum 30° | Ankle angle increases 36.845° | Y |
| The brace's material does not excessively add to the circumference of the ankle | Measure circumference of device, ensure it is less than 2.5 inch larger than ankle circumference | 11 11/16 in -9 5/16 in=2 3/8 in | Y |
| Weight | Weighs no more than 20 ounces | 17.45 oz | Y |
| The ankle support will have no sharp or abrasive parts. | Sand all parts | Smooth edges | Y |
| Withstand static and impact forces associated with user walking | 200 lb tension/compression test for Cobra Buckle, Tamarack connector, and sheet metal assembly | Withstood 277.9 lbs in tension, 200 lbs in compression. Polypropylene used for current application, impact forces not tested. | Y |
| Cost | Less than $300 | $176.58*<br>*Does not include shipping and handling | Y |
| Attachments withstand pressures of foot when in dorsiflexion and plantar flexion. | 200 lb tension/compression test for Cobra Buckle, Tamarack connector, and sheet metal assembly | Withstood 277.9 lbs in tension, 200 lbs in compression. | Y |
| Prevent hyperextension of the knee. | Measure angle of knee between mid-stance and toe off of gait cycle. Ensure less than 23° | >23° | N |

*Bill of Materials*

**Table 14. Bill of materials**

| Item # | Part Number | Part Name | Description | Quantity | Units | Supplier/ Manufacturer |
|---|---|---|---|---|---|---|
| 1 | B742-85-M | Tamarack Joint | Keeps foot in flexion during gait | 2 | 1 | Kingsley |
| 2 | 29705T31 | Light-Duty Cam Buckles | Strap adjustment | 2 | 1 | McMaster Carr |
| 3 | 3444T21 | Low Stretch Polyester Webbing | Strap to hold the brace on the leg | 2 | 1 | McMaster Carr |
| 4 | 2898K42 | Polypropylene Sheet (3/16") | To make the brace | 1 | 1 | McMaster Carr |
| 5 | 9015T131 | Sheet Metal (Aluminum) | Rigid attachment to the brace for the buckles | 1 | 1 | McMaster Carr |
| 6 | PLH-SRB-COB-000 | GT COBRA Quick Release Buckle | Allows for release from flexion to extension | 2 | 2 | AustriAlpin |
| 7 | 86375K111 | Resilient Polyurethane Foam Sheet | Creates a cushion between the user and the polyethylene | 1 | 1 | McMaster Carr |
| 8 | 94459A150 | Heat-Set Inserts for Plastic | Allows the screw to connect to the polypropylene | 8 | 1 | McMaster Carr |
| 9 | 11547539 | Metric 18-8 Stainless Steel Hex Drive Flat Head Screws | Provide connection between sheet metal and brace | 8 | 1 | Fastenal |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10 | 90592A090 | Metric Medium-Strength Steel Hex Nuts | Provide the screw stability for the joint metal attachment | 4 | 1 | McMaster Carr |
| 11 | 93475A230 | 18-8 stainless steel washers | Provide a strong hold for the bolt in the plastic | 4 | 1 | McMaster Carr |

*Failure Mode and Effect Analysis (FMEA)*

**Table 15. Failure Mode and Effects Analysis (FMEA)**

| Component Name | Possible Failure Mode | Type | Cause of Failure | OCC | DET | SEV | RPN | Effect of Failure on System | Failure Improvement Alternative Actions (actions to fix the problem… ) |
|---|---|---|---|---|---|---|---|---|---|
| Double Sided Buckle | broken | C | improper use of the buckle, or being crushed under high pressure could cause the buckle to break | 4 | 6 | 6 | 144 | would keep ankle in plantar flexion, wouldn't provide dorsiflexion support | perform stress tests on the material used to make the buckle to make sure it won't break under slightly higher pressures than would normally be applied |
| Velcro | worn | C | inadequate use, user applies too much wear and tear, dirt and water | 5 | 5 | 5 | 125 | could impact the device being held in place | testing the velcro under unusual circumstances to ensure reliability |
| Polyester strap | worn | C | extra strain applied to it due to improper use | 2 | 3 | 5 | 30 | wouldn't hold the leg piece and the foot piece together when the buckle is released to allow plantar flexion | repeated stress tests to be sure that the strap can handle repeated use and stresses |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Tamarack Joint | worn | M | Manufactured incorrectly | 2 | 2 | 6 | 24 | would prevent the ankle from being held in dorsiflexion | preform repeated stress tests to be sure the joint won't fail after repeated use |
| Polypropylene | cracked | W | improper manufacturing of material, wears out too easily | 3 | 1 | 5 | 15 | if the crack grows, device could be unusable | stress tests to be sure the polypropylene will withstand the basic pressures applied by the user |
| Metal strap loop | bent | C | improper use, being used for more than the design allows | 3 | 1 | 5 | 15 | would impact the strap, could make uncomfortable or difficult to use strap | pressure test to be sure the loop won't bend under unusual pressure |
| Rivet | bent | C | improper use, user applies too much pressure, using for improper activities | 3 | 1 | 5 | 15 | would impact the release from dorsiflexion | stress test to be sure that repeated use and release of the joint won't affect the piece |


**Figure 12. Photo of senior project team and sponsors.**

From left to right: Kim (sponsor), Denise (patient), David West, James, Erik, and Christine.